REMARKS

Claims 74-82 are now pending. Claim 80 has been amended, and claim 83 has been canceled.

Claims 74-82 stand rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. The Office Action asserts that certain words and phrases used in the claims are not supported in the specification. The remarks herein explain how and where the words and phrases at issue are supported.

Claim 74: "prioritize said patient's complaints." "Triage" is another term for prioritizing patient complaints. Triage by the inventive software is taught at page 36 (see the heading "Initial triage of patient complaints"), and page 37 ("If the answers indicate a situation that warrants immediate attention by a physician, yes at 290"). See also FIG. 4B. These embodiments relate to information entered by a nurse. Embodiments relating to information entered by a patient are taught beginning at page 38. See, for example, page 38, line 8 ("The next order of business is a sequence of triage questions, block 340."); page 38, line 18 ("These triage data allow appropriate branching to specific modules to characterize these problems of central importance to the patient, 355"); page 43, line 4 ("The next sequences involve implementation of a thorough clinical evaluation to pursue symptoms elicited in the triage module."); and page 90, line 10 ("Patient problems are presented in order of greatest concern to the patient, as determined when each problem was characterized (block 815).").

Claim 74: "major complaints are ranked by relevance." See above – especially page 90, line 10 ("Patient problems are presented in order of greatest concern to the patient, as determined when each problem was characterized (block 815)."

Claim 74: "interview configuration profile." This phrase is actually defined by claim 74 itself. An interview configuration profile determines inquiry scope and depth for a patient interview. Inquiry scope specifies a set of interview topics to be covered in the interview, and inquiry depth specifies a level of detail for a characterization of elicited symptoms. Thus, the only question is whether the original disclosure teaches and

enables specifying a set of interview topics and a level of detail for a characterization of elicited symptoms. These features are enabled throughout the specification. See, for example:

(1) P. 29 relates to adapting an interview to patient characteristics – see "Efficient patient management requires adapting management strategies to the attributes of individual patients" (p. 29, lines 11-12). "To this end, the invention accommodates real-time adaptation of communications strategies, question sets, and management algorithms for patient characteristics, including age, gender, socioeconomic and educational background and medical history." (p. 29, lines 15-18)

(2) P. 31, line 6-8: "With a modular design, physician editors can create and refine the questions, other displays, and the clinical strategy without reprogramming the system code itself."

(3) Physician-editor's toolkit on page 80 et seq., describes tools to allow physician/editor to control the flow of the interview (script editor, which supports "creation of scripts that control the flow of the presentation to the patient, screening for potentially important symptoms" though "other interfaces could be utilized to accomplish the same goal."

(4) "Interactions with the system are individualized based on prior patient responses and patient characteristics." p. 20, lines 4-5)

(5) P. 81, lines 11 -20: a glossary editor "supporting parallel scripts adapted for patient characteristics."

(6) P. 81, lines 16-17: "Targeting questions to subgroups is more effective that utilizing broad-spectrum questions for all patients."

(7) P. 82, lines 7-8 (the pattern set editor): "This simple interface permits the physician-editor to define complex patterns within a large universe of possibilities." P. 82, lines 10-12: it also "allows the physician editor to refine the criteria for identifying symptom complexes or testing other criteria based upon experience with patients and physician-users."

(8) P. 82, 17-19: "Internally, a master interpreter controls the execution of clinical application comprising scripts, screens, glossaries and pattern sets."

(9) P. 83, lines 12-13: "software structure provides an extremely flexible, scalable approach"

Claim 74: "configuration profile." See "interview configuration profile."

Claim 75: "index symptom."

(1) The analogous term "index complaint" is used on p. 43, lines 6-7: "To fully elucidate these problems, all of the screening questions are asked pertaining to the index complaint."

(2) FIG. 8 illustrates an example index symptom (heartburn), and how it is characterized.

(3) Index symptom, generally, refers to what a patient experiences as the main symptom that may relate to other symptoms. This is addressed in at least two sections:

a) The section on eliciting an obscure problem, at pp. 55-57.

b) The section on discriminating multiple, overlapping provisional problems, at pp. 57-60.

Claim 75: "index symptoms." See index symptom.

Claim 75: "redundant characterization of detail is skipped."

(1) P. 43 (section on overall screening strategy), lines 6-10: "To fully elucidate these problems, all [6] of the screening questions are asked pertaining to the index [7] complaint. Branches with more detailed questions are pursued as [8] appropriate. After questions relating to the primary complaint are [9] asked, comprehensive screening is performed to assure that potentially [10] important symptoms are detected and characterized."

(2) P. 44, line 15-16: "Branching is utilized so that detailed characterization is only pursued if screening questions are positive."

(3) The concept of pursuing branches as appropriate should be read with the points made below regarding minimizing patient frustration and confusion

(4) P. 56, lines 9-10: "If the symptoms are the same, no further characterization will be performed, block 868." This is because further characterization would be *redundant*. See also p. 59, lines 2-5, where a patient who reports two symptoms are connected will only be asked to characterize features that differ.

Claim 75: "risk of frustrating."

(1) P. 43, line 19: "Strategies are implemented to minimize patient confusion...."

(2) P. 19, line 15: avoiding patient frustration.

(3) P. 19, line 17: "minimize patient confusion."

(4) P. 45, lines 5-7: "The strategy for screening includes features to minimize patient frustration that would otherwise result when attention is focused on common symptoms that do not really trouble them."

Claim 76: "functional status."

Functional status is an aspect of quality of life assessment; since quality of life is discussed in the specification, functional status is inherently included. Functional status reflects the individual's ability to accomplish what they need and want to do, and is an integral part of quality of life assessment.

(1) P. 21, lines 12-14: "Quality of life measurement focuses on the frequency and severity of symptoms and disruption of function and activities of daily living."

(2) P. 63, line 14: "functional impact."

(3) P. 64, lines 15-16: "level of functioning and activities of daily living" (this is equivalent to functional status).

Claim 76: "concurrent symptom groups."

(1) P. 55, lines 16-20, regarding eliciting an obscure problem. It is common for patients to have a symptom complex that obscures a second problem. Identifying this second problem may facilitate the management process. The invention may implement several mechanisms to identify problems obscured by the presence of multiple symptom complexes (see block 850 in FIG. 7C). These steps may be implemented at the conclusion of a characterization sequence (block 825, FIG. 7B).

(2) P. 56, line 1-3: "Concurrent symptom groups" is another term for "overlapping symptom complexes."

(3) P. 56, line 5-6: Symptom groups that are present at the same time, i.e., concurrent, may be independent or part of the same underlying condition. "The patient might not know these are separate [or connected] until they are teased apart" by the interview process.

(4) p 57, line 14: "Discriminating multiple, overlapping provisional problems."

Claim 76: "separate scores are calculated for each of said symptom groups."

(1) The specification discusses at length how symptom groups are discerned in the section on eliciting an obscure problem (pp. 55-57) and the section on discriminating multiple, overlapping provisional problems (p. 57-60).

(2) P. 63, lines 12-14: "When a patient scores moderate or high values on the scale for a particular domain, the degree of distress and functional impact is assessed, block 1060." All domains for symptoms and QOL are scored.

(3) P. 55, lines 11-13: "With the problem now defined, QOL measures are applied that determine the degree of impact on daily functions. . . ."

Claim 77: "functional status." See claim 76.

Claim 77: "generic domains."

Quality of life comprises several domains, which can be looked at generally for the whole patient or for a per condition/symptom complex. "Generic" refers to general domains that could apply to any number of health conditions, in contrast to "condition-specific" domains that only apply to a specific condition or group of conditions.

(1) P. 21, lines 15-17: mentions "general and condition-specific health status." Health status refers to quality of life.

(2) P. 21, lines 13-14: mentions many quality of life domains: "the frequency and severity of symptoms and disruption of function and activities of daily living." This discussion continues on lines 16-17: quality of life "measures have been validated for both general and specific health status." And further, on lines 17-19: "CPM will develop, rigorously validate, and implement reliable and practical quality of life measures."

(3) The specification discusses grouping psychologic symptoms into domains, p. 63, lines 7-8: "Psychologic symptoms are grouped into domains."

(4) See also p. 63, lines 12-14: "When a patient scores moderate or high values on the scale for a particular domain, the degree of distress and functional impact is assessed, block 1060."

Claim 78: "functional status." See claim 76.

Claim 80 is amended with this response, but the amendments are minor and have the same support as provided below.

Claim 80: "different levels of severity are assigned different scores."

This is largely the same as using a scale to collect the patient response regarding severity, as discussed regarding claim 76. In this case more is being done with the data, but the process is largely the same.

(1) P. 45, lines 7-10: "Matrix screens are used. . . so patients have the option of indicating how frequently they are troubled with the problem (e.g., never, rarely, some, a lot, always)." (Here severity corresponds to frequency of trouble.)

(2) P. 63, lines 3-5 in the QOL section: "These choice options can be scalar or categorical to measure how frequent and troublesome these domains are for the patient."

Claim 80: "Individual scores are reported to facilitate interpretation by a physician."

Regarding scores, see above. Also see:

(1) P. 12, lines 18-20: "to provide integrated measures of patient outcomes and physician process that can be utilized to investigate the success of specific treatments and overall management strategies."

(3) P. 17, lines 4-6: "interactive computer system that systematically records and analyzes relevant information about the patient's health."

(4) P. 17, lines 17-18: the system "focus[es] the health care encounter on active problems."

(5) P. 21, lines 5-6: "Assessing the quality and consequences of the treatment process requires quantifiable endpoints."

(6) P. 25, lines 20-21: system capacity for "flagging and prioritizing important problems."

(7) P. 39, line 14: a "system response analyzer" tracks inconsistent responses.

(8) P. 51, lines 8-9: "Implementation of Boolean logic is in a flexible format that supports continual refinement."

(9) Boolean tests are mentioned at p. 64, line 7; also, "implementation of Boolean logic is in a flexible format that supports continual refinement" (p. 51, lines 8-9).

(10) P. 65, lines 13-17: patients will be asked whether problems are "of high, medium, or low priority from their perspective. In addition, certain system criteria apply that automatically elevate some problems to high priority based on clinical importance. . ."

Regarding physician interpretation, see:

a) P. 2, line 12: a goal/function is to "create a computer system that facilitates patient-centered care" – and within that, on p. 2, line 18 to p. 3, line 1, to "collect and present the patient's health questions and concerns to physicians" and on p. 3, line 4, to "assess patient response to and satisfaction with care."

b) P. 19, line 5-9: "These data are then analyzed in real time using a sophisticated system for implementing Boolean logic, based upon expert-determined criteria for identifying symptom complexes and provisional problems. Using this mechanism, the system can discern multiple and overlapping problems."

c) P. 26, lines 14-16: "The invention is designed to support incorporation of patient-centered care into routine practice by integrating these patient-centered elements. . ."

d) P. 26, line 22 to p. 27, line 3: "Issues relating to patient-centered care, such as psychosocial factors, health attitudes, illness concerns and questions, are presented to the physician as provisional problems."

e) P. 73, lines 9-15: "The inventive system uses exit interview data to further support patient-centered care by providing individualized feedback to the physician on elements of the patient-physician interaction and patient health attitudes. These data are collected from the patient and fed to the physician on a per encounter basis. This information serves to educate physicians on the impact of their actions, effectiveness of their communication, and patient response over time."

Claim 81. "automate patient recruitment for research trials." This is another way of saying that "an interactive module that includes educational sequences and evaluation

questions will be developed for collecting informed consent of patients" (p. 41, lines 12-17).

Claim 81: "query patients." P. 41, lines 12-17 describes "collecting informed consent from patients," which is querying - or asking - them about their willingness to participate in research. This is the process of "collecting informed consent of patients" (p. 41, lines 12-17).

Claim 81: "receive eligibility requirements for research studies" and "qualify patients for a research study." This is inherent in the "new paradigm for informed consent" that uses data collected from patients in the routine computer interview to ascertain whether the patient has symptoms that qualify them for clinical investigation. This also applies to "inform a patient and a research coordinator of studies for which said patient is eligible."

Claim 83 has been canceled – but not because it lacked support in the specification. Applicant reserves the right to claim the subject matter of claim 83 in other applications claiming priority to the present application.

In light of the above highly detailed explanation, Applicant respectfully submits that all claim rejections have been overcome.

No fee is believed due in connection with this Response (other than the RCE and extension of time fees separately authorized). If any other fee is required, please charge such fee to Deposit Account No. 50-0310.

Dated: February 12, 2007

Respectfully submitted,

Steven D. Underwood
Reg. No. 47,205
MORGAN, LEWIS & BOCKIUS LLP
Customer No. 009629
212-309-6196